ALLEZ SPINE

K072678

510(k) Summary

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

JUL - 2 2008

Contact:	Mr. Hartmut Loch Regulatory Consultant c/o Allez Spine, LLC. 2301 DuPont Drive, Suite 510 Irvine, CA 92612
Trade name:	*LAGUNA™ Size 8 Pedicle Screw*
Common name:	Spinal Fixation System
Classification name:	Spinal Interlaminal Fixation Orthosis - § 888.3050 (KWP) – Class II Orthosis, Spinal Pedicle Fixation - § 888.3070 (MNI) – Class II Orthosis, Spondylolisthesis Spinal Fixation - § 888.3070 (MNH) – Class II Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease - § 888.3070 (NKB) – Class III All Orthopedic Device Panel 87
Product Code:	KWP, MNI, MNH & NKB
Device Description and Characteristics:	The *LAGUNA™ Size 8 Pedicle Screws* are intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space in conjunction with the Allez Spine LAGUNA™ Polyaxial Pedicle Screw System. The LAGUNA™ Spinal System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case. The Allez Spine LAGUNA™ Polyaxial Pedicle Screw System (K050060) was cleared for marketing on May 4, 2005. The *LAGUNA™ Size 8 Pedicle Screws* are available in eleven sizes ranging from 30 mm to 100 mm are fabricated from medical grade titanium alloy described by such standards as ASTM F136 or ISO 5832-3 or 5832-2.
Equivalence:	*LAGUNA™ Size 8 Pedicle Screws* are substantially equivalent to the LAGUNA™ Pedicle Screw System K050060 - S/E May 4, 2005
Indications:	The LAGUNA™ Spinal System is intended to be used as an adjunct to fusion using autograft or allograft in posterior, non-cervical pedicle fixation for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.fracture or dislocation); spinal stenosis; curvatures (i.e.scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.
Performance data:	Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

Allez Spine, LLC
% Mr. Hartmut Loch
Regulatory Consultant
2301 DuPont Drive, Suite 510
Irvine, CA 92612

Re: K072678
Trade/Device Name: LAGUNA™ Size 8 Pedicle Screw
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: May 28, 2008
Received: June 3, 2008

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K072678

Device Name(s):

LAGUNA™ Size 8 Pedicle Screw

Indications for Use:

The LAGUNA™ Spinal System is intended to be used as an adjunct to fusion using autograft or allograft in posterior, non-cervical pedicle fixation for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.fracture or dislocation); spinal stenosis; curvatures (i.e.scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K072678